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October 17, 2018

VIA ECF

Honorable Claire C. Cecchi, U.S.D.J.
United States District Court
M.L. King, Jr. Federal Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: In Re Biogen '755 Patent Litigation
Civil Action No. 10-2734 (CCC) (MF)

Dear Judge Cecchi:

I write on behalf of Bayer to respectfully request the certification for interlocutory appeal under 28 U.S.C. § 1292(b) of this Court's January 9, 2018 Order, ECF No. 893 (the "MSJ Order"), denying Bayer's motion for summary judgment of invalidity under the doctrine of obviousness-type double patenting over Biogen's U.S. Patent No. 6,127,332, ECF No. 522 ("Bayer's OTDP motion").

On October 9, 2018, Serono filed a notice of appeal. ECF No. 1060. Pursuant to that notice, Serono is appealing the Court's September 7 Order regarding various renewed motions for judgment as a matter of law filed by Biogen and Serono, ECF Nos. 1043, 1044, as well as "any and all other adverse judgments, orders, opinions, rulings, and findings that merge therein or are pertinent or ancillary to the foregoing, except with respect to damages issues." ECF No. 1060.

In light of Serono's appeal and in the interest of judicial economy, the Court should certify the MSJ Order, which would permit the Federal Circuit to address, along with Serono's appeal, other related pure questions of law that can resolve this complex litigation, which has now spanned more than eight years. The Court's certification for interlocutory appeal would not delay the litigation between Bayer, Novartis, and Biogen, which will not re-commence until after another trial between Serono, Pfizer, and Biogen. *See* ECF No. 1058 (Biogen's proposed judgment, noting that "the Court will schedule a jury trial to determine the amount of damages

owed to Biogen by Defendants Serono and Pfizer, followed by a jury trial of all issues between Biogen and Bayer and Novartis").

Bayer requests that the Court's order denying summary judgment be certified for appeal pursuant to Section 1292(b) as to the following legal questions regarding Bayer's OTDP motion:

a) Whether a two-way test can be applied where it is undisputed that the U.S. Patent and Trademark Office was not solely responsible for delay during the patent's prosecution.

b) Whether summary judgment on obviousness-type double patenting can be denied on the basis that the movant's expert did not provide an opinion as to the ultimate legal question of patentable distinctness, where the evidence is undisputed that the limitations of the claim are met by the reference claim.

Pursuant to 28 U.S.C. § 1292(b), an order that is otherwise not appealable may be certified for interlocutory appeal when (1) it involves "controlling question[s] of law," (2) there are "substantial grounds for difference of opinion," and (3) the "immediate appeal from the order may materially advance the ultimate termination of the litigation." *See, e.g.*, *Shire LLC v. Sandoz, Inc.*, 345 F. App'x 535 (Fed. Cir. 2009) (granting the petition to appeal the district court's summary judgment order). Though the Court also found that there were factual disputes that precluded the granting of Bayer's OTDP motion, the resolution of the aforementioned issues in Bayer's favor would require summary judgment to be granted, regardless of the factual disputes found by the Court, because those factual issues would be irrelevant if the legal issues raised by Bayer were resolved in its favor.

As the Third Circuit has noted, Section 1292(b) certification is appropriate in cases like this one, "where an immediate appeal may avoid protracted and expensive litigation." *Milbert v. Bison Labs., Inc.*, 260 F.2d 431, 433 (3d Cir. 1958); *see also Katz v. Carte Blanche Corp.*, 496 F.3d 747, 755 (3d Cir. 1974) ("[S]aving of time of the district court and of expense to the litigants was deemed by the sponsors to be a highly relevant factor."). And here, each of the three prongs under Section 1292(b) is satisfied:

First, the questions presented are controlling questions of law, as the final resolution of the questions "would advance the determination of the litigation." *Santos v. Carrington Mortgage Servs., LLC*, 2015 WL 11071479, at *1 (D.N.J. Sept. 2, 2015); *see also Katz*, 496 F.3d at 755 (a question can be controlling if it "is serious to the conduct of the litigation, either practically or legally"). In the instant case, a Federal Circuit decision on the issues presented could reverse this Court's denial of summary judgment and direct this Court to enter final judgment in favor of Bayer. *See Carroll v. Delaware River Port Auth.*, 2016 WL 727117, at *1 (D.N.J. Feb. 23, 2016) (finding controlling question of law where the appellate court's reversal

of lower court's opinion would direct lower court to enter judgment for defendant); *In re Chocolate Confectionary Antitrust Litig.*, 607 F. Supp. 2d 701, 705 (M.D. Pa. 2009) (holding question presented to be a "controlling issue of law appropriate for appellate certification" where "[d]isposition of the motions would unquestionably change were [the] question [presented] answered in the negative"); *Alexander v. Washington Mut., Inc.*, 2008 WL 3285845, at *3 (E.D. Pa. Aug. 4, 2008) ("Because judgment would be reversible on final appeal if this determination is erroneous and a different resolution of the issue would eliminate the need for trial, I conclude that it involves a controlling question of law."). In other words, the issues presented are controlling questions, as their resolution in Bayer's favor would end or materially advance this complex patent case and obviate the need for a second trial in this litigation. *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553, 599 (E.D. Pa. 2008) ("a controlling question of law is one that has the potential of substantially accelerating disposition of the litigation") (internal quotation marks and citation omitted); *see also* 16 Charles A. Wright *et al.*, Fed. Prac. & Proc. § 3930 (3d ed. 2012) ("a question is controlling, even though its disposition might not lead to reversal on appeal, if interlocutory reversal might save time for the district court, and time and expense for the litigants").

Second, substantial grounds for difference of opinion exist where there is "genuine doubt or conflicting precedent as to the correct legal standard." *Royal Ins. Co. of America v. K.S.I. Trading Corp.*, 2006 WL 1722358, at *3 (D.N.J. June 19, 2006). "Conflicting and contradictory opinions can provide substantial grounds for a difference of opinion," as can "the absence of controlling law on a particular issue." *Knipe*, 583 F. Supp. 2d at 600. The inquiry here is not whether the Court's "decision bears the correct analysis and result," but rather whether the "Court finds that the question involved here is admittedly complicated and sufficiently close that reasonable minds could disagree with the Court's conclusion." *Levine v. United Healthcare Corp.*, 285 F. Supp. 2d 552, 560 (D.N.J. 2003).[1]

As to the first legal question, the Court noted that the "undisputed facts show that, between April 1982 and May 1995, Biogen was partially responsible for the timing of the '755 patent's issuance." ECF No. 892 ("MSJ Op."), at 23; *see also id.* at 24 ("the undisputed record shows that Biogen was at least partially responsible for the delay"). The parties disputed whether Biogen's failure to prosecute claims earlier precludes application of the two-way test. Bayer argued that because of Biogen's delay in prosecution, a two-way test could not apply, under Federal Circuit precedent. *See* ECF No. 597 ("Bayer Reply Br."), at 4-5 (citing cases);

[1] Indeed, in *Levine*, the Court noted that it still believed its decision was correct, but because of the complicated issue presented, it agreed to certify the issue for interlocutory appeal. *Levine*, 285 F. Supp. 2d at 260; *see also Zenith Radio Corp. v. Matsushita Elec. Indus. Co.*, 1979 WL 1689, at *2 (E.D. Pa. Aug. 21, 1979) (granting request for Section 1292(b) appeal even where court "firmly believe our conclusion to be correct").

MSJ Op. at 23-24. Biogen, however, contended that the relevant test is whether Biogen controlled the patent application's "rate of prosecution," and not whether the extension of patent term was solely the fault of the PTO. ECF No. 559 ("Biogen Opp."), at 16-17 (quoting *In re Fallaux*, 564 F.3d 1313, 1316 (Fed. Cir. 2009)); MSJ Op. at 24-25. The Court, by concluding that there were factual issues that prevented determining whether a one-way or two-way test is appropriate, necessarily held, as a matter of law, that Biogen's "partial[] responsib[ility]" for delay in prosecution did not preclude the application of a two-way test. MSJ Op. at 25. Regarding whether a claim is invalid for obviousness-type double patenting, the Federal Circuit has held that "[t]he determination of whether a one-way or two-way analysis applies is also a question of law . . . ." *In re Fallaux*, 564 F.3d 1313, 1316 (Fed. Cir. 2009). In cases like this one, where the parties do not dispute when the applications were filed, "but rather the conclusion to be drawn from those dates," *In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997), the Federal Circuit has drawn those conclusions—and determined the appropriate test to apply—as "a question of law," *In re Hubbell*, 709 F.3d 1140, 1149 (Fed. Cir. 2013). While the parties had factual disputes about Biogen's delays, those disputes are irrelevant here: If the Federal Circuit finds that a patentee's partial responsibility for delay in prosecution prohibits the application of the two-way test, then a one-way test must apply in this case. Although Bayer believes its position on this question is correct, the parties' competing positions and citations of Federal Circuit opinions highlight that this issue is "complex and subject to debate," and thus should be certified for interlocutory appeal for resolution by the Federal Circuit. *Levine*, 285 F. Supp. 2d at 566; *see also id.* at 560 (certifying another issue presented for interlocutory appeal where the issue is "admittedly complicated and sufficiently close that reasonable minds could disagree").

As to the second question, the Court adopted Biogen's position that because "Bayer's experts had offered no opinions as to whether claim 1 is patentably distinct over the '332 patent claims," Bayer had not "submit[ted] . . . clear and convincing evidence of facts underlying invalidity [for OTDP] that no reasonable jury could find otherwise," and thus, summary judgment could not be granted even under a one-way test. MSJ Op. at 26 (citing Biogen Opp. at 30-33). But the Court could reach this conclusion only by necessarily resolving an underlying question of law that is disputed. Bayer contends that as a matter of law, it does not matter if a reference patent claims an anticipating species—here, non-human hosts—along with other, non-anticipating species, based on *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368 (Fed. Cir. 2005). Reply Br. at 14-15. Biogen cites *Eli Lilly & Co. v. Teva Parenteral Meds.*, 689 F.3d 1368 (Fed. Cir. 2012), in arguing the opposite. Although Bayer believes its view is correct, this clearly is an issue as to which there is at least "genuine doubt" as to Biogen's position, and it is therefore ripe for certification. If the Federal Circuit were to agree with Bayer's position, that decision would be dispositive, because expert testimony on the ultimate issue of double patenting would not be required. Bayer showed through the undisputed testimony of Biogen's own expert, Dr. Green, that (1) a mutein of claims 5 and 8 of the '332 patent would hybridize to a DNA insert of claim 1 of the '755 patent, and (2) that "there's a species/genus relationship" between the claims such that "the use of the specific mutein claimed in the '332 patent falls within or is a

subset of the use of interferon-beta and its muteins claimed in the '755 patent." Reply Br. at 11. Thus, the claims of the '332 patent anticipate claim 1 of the '755 patent and Bayer is entitled to judgment as a matter of law.

Finally, as to the third requirement, courts evaluate whether an appeal would "eliminate the need for trial" or "eliminate complex issues so as to simplify the trial." *Orson, Inc. v. Miramax Film Corp.*, 867 F. Supp. 319, 322 (E.D. Pa. 1994). As discussed earlier, a reversal of this Court's order would immediately end the litigation, and resolution of either of the issues could substantially simplify a trial between Bayer, Novartis, and Biogen. In analyzing this third requirement, courts "should focus on the efficient use of judicial resources." *Hess v. A.I. DuPont Hosp. for Children*, 2009 WL 2776606, at *4 (E.D. Pa. Aug. 29, 2009). In *Hess*, the court certified its summary judgment order in part because doing so would "result in either dismissal or clarification of the law to be applied at trial, which in turn will simplify the administration of the trial and reduce the likelihood of a post-trial appeal. Either of these outcomes will result in a more efficient use of judicial resources than denying the Petition [to Appeal] and proceeding to trial." *Id.*

Certification of the dispositive issues presented in this case, which the Court noted in an earlier opinion involves "a variety of complex issues in a case involving complicated technology," ECF No. 742, at 8, is particularly appropriate. *See Zenith Radio Corp. v. Matushita Elec. Indus. Co.*, 494 F. Supp. 1190, 1244 (E.D. Pa. 1980) ("the certification procedure of 28 U.S.C. § 1292(b) was intended specifically to expedite 'big' cases . . . ."); *see also* H. Rep. 85-1667, at 1-2 (1958) ("There should be some way, for example, in long-drawn-out . . . cases, to dispose of vital questions which are raised in the trial without having to wait for the taking of testimony and the conclusion of trial before the questions can finally be determined on appeal.").

As noted above, granting this requested certification would not delay resolution of the case against Bayer and Novartis. The Court has already determined that the trial in the Bayer case will come after the trial in the Serono case, and accordingly, Biogen's proposed judgement provides that "the Court will schedule a jury trial to determine the amount of damages owed to Biogen by Defendants Serono and Pfizer, followed by a jury trial of all issues between Biogen and Bayer and Novartis." ECF No. 1058. The issues presented thus should be considered by the Federal Circuit in conjunction with the pending appeal, as this approach will cause no delay in the litigation and conserve judicial resources. *See Regents of Univ. of Ca. v. Dako N. Amer., Inc.*, 477 F.3d 1335, 1337 (Fed. Cir. 2007) (granting petition for permission to appeal pursuant to Section 1292(b) given the "efficient use of judicial resources"). Indeed, granting Bayer's request for certification now could avoid years of litigation that could prove wasteful in this complex patent case.

For the foregoing reasons, Bayer respectfully requests that the Court, pursuant to 28 U.S.C. § 1292(b), certify the controlling questions of law in the Court's order denying summary judgment as to Bayer's OTDP motion.

Respectfully submitted,

GREENBAUM, ROWE, SMITH & DAVIS LLP

/s/ Robert M. Goodman

ROBERT M. GOODMAN

RMG/CBK
cc: Counsel of Record [via ECF]